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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,721	03/22/2005	Hee-Chan Kim	1508-3 PCT/US	6970

23869 7590 12/12/2008
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EXAMINER	
RIPA, BRYAN D	
ART UNIT	PAPER NUMBER
4111	
MAIL DATE	DELIVERY MODE
12/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,721	KIM ET AL.	
	Examiner	Art Unit	
	BRYAN D. RIPA	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1, 10 and 15 are objected to because of the following informalities.

Regarding claims 1 and 10, the preliminary amendments in claims 1 and 10 used the phrase “biomedical substrate” as opposed to the earlier used phrase “biochemical substrate" contained in the preamble. This appears to be a minor typographical error. The examiner requests the applicant to make the appropriate changes to ensure that both phrases correlate.

Regarding claim 15, there is a typographical error in the spelling of disulfide.

Claims 4 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The recitation in the preamble describing the claimed electrode as “mesoporous platinum” is interpreted by the examiner as limiting the electrode structure such as to require the presence of a mesoporous platinum layer on the electrode. The MPEP states that, “[a]ny terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation.” See MPEP 2111.02 citing to *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Moreover, it is well accepted in the art that the term “mesoporous” specifically refers to pores with a diameter between 2 and 50 nm. See Nomenclature of Structural and

Compositional Characteristics of Ordered Microporous and Mesoporous Materials with Inorganic Hosts, L.B. McCusker et al., Pure & Appl. Chem., Vol. 73, No. 2, 381–394, 382 and Recommendations for the Characterization of Porous Solids, J. Rouquerol et al., Pure & Appl. Chem., Vol. 66, No. 8, 1739–1758, 1745 (stating that the IUPAC definition of mesopores is pores with a diameter between 2 and 50 nm).

As a result, since the recitation of "mesoporous" in the preamble is a claim limitation and since the term specifically denotes pores having a diameter between 2 and 50 nm, claims 4 and 13 do not further limit the independent claims from which they depend, respectively claims 1 and 10.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1–9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartlett et al. (U.S. Pat. No. 6,503,382) (hereinafter referred to as "Bartlett").

Regarding claim 1, Bartlett teaches a mesoporous platinum electrode with an electrode (col. 5 lines 14–16), a mesoporous platinum layer (col. 5 lines 33–37; col. 6 lines 25–31), and the lack of an enzyme immobilized on the electrode (col. 5 lines 14–37).

In applying the mesoporous platinum layer to an electrode, Bartlett never requires the addition of an enzyme. Rather, Bartlett discusses the use of a substrate, i.e. an electrode when applying the mesoporous platinum layer to an electrochemical application, and the deposition of the mesoporous platinum layer to that substrate. See col. 5 lines 14–37; col. 9 lines 23–35. Furthermore, although Bartlett does teaches the possibility of further treatment of the mesoporous platinum layer by an enzyme, Bartlett describes this further treatment as optional and was clearly not limiting the disclosure of the mesoporous platinum layer to further treatment, whether it be treatment with an enzyme or otherwise. See col. 5 line 53–col. 6 line 3.

Regarding claims 2 and 3, Bartlett teaches the use of gold, a noble metal, and carbon as a suitable substrate or electrode. See col. 5 lines 14–16.

Regarding claim 4, Bartlett teaches the pore size of the platinum layer being between 2–50 nm. See col. 6 lines 25–30.

Regarding claim 5, Bartlett teaches the mesoporous platinum layer having a thickness anywhere between 1 to 200,000 nm, but preferably between 10 to 20,000 nm. See col. 5 lines 33–37.

Regarding claim 6, see discussion regarding claim 1.

Please note, in claim 6 applicants are attempting to further limit the type of biochemical substrate that the claimed electrode is to be used with. The statement in the preamble “for detecting biochemical substrate” is a statement of intended use. See MPEP 2111.02 (II). The MPEP clearly states, “[a] claim containing a ‘recitation with respect to the manner in which a claimed apparatus is intended to be employed does

not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim." See MPEP 2114 citing *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Consequently, the additional recitations of claim 6 are not given patentable weight and claim 6 is therefore rejected on the same basis as claim 1.

Regarding claims 7–9, see discussion regarding claim 1.

Please note, claims 7–9 depend from claim 6 and attempt to further limit the intended use statement beyond that of claim 6. However, the same rational applies to the additional intended use limitations contained in these claims as applied to claim 6. See discussion above regarding claim 6. Consequently, the additional recitations contained in claims 7–9, just as with claim 6, are not given patentable weight and are therefore rejected on the same basis as claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10–20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marincic et al., "Electrochemical Glucose Oxidation on a Platinized Platinum Electrode in Krebs-Ringer Solution" J. Electrochem. Soc.: Electrochemical Science and Technology 126 (1), 43–49 (1979) (hereinafter referred to as "Marincic") in view of Bartlett, Evans et al., "Detection of Hydrogen Peroxide at Mesoporous Platinum Microelectrodes" Anal. Chem. 74, 1322–1326 (2002) (hereinafter referred to as "Evans"), and Elliott et al., "Platinum Microelectrodes with Unique High Surface Areas" Langmuir 22, 15 pages 7411–7415 (1999) (hereinafter referred to as "Elliott").

Regarding claim 10, Marincic teaches a method for detecting a biochemical substrate comprising the steps of taking a platinum electrode without the presence of an immobilized enzyme (see page 44), contacting a sample solution containing the biochemical substrate with the platinum electrode (see 44), and detecting a response

current generated by applying a voltage to the platinum electrode (see 44–45). Marincic, however, does not teach the use of a mesoporous platinum electrode in the disclosed method for determining the concentration of the biochemical substrate.

However, Bartlett, as mentioned previously, teaches the use of a mesoporous platinum layer on electrodes for use in electrochemical sensors (see col. 5 lines 14–16). It would have been obvious to one of ordinary skill in the art to use the mesoporous platinum electrode, with its greatly enhanced surface area, to increase any kinetically controlled reactions that take place on the platinum. See Evans page 1323.

The combination of prior art elements according to known methods is likely to be obvious when yielding predictable results. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395–97 (2007) (See MPEP 2143).

Consequently, it would have been obvious to one of ordinary skill in the art to use the method of Marincic with the mesoporous platinum electrode as taught in Bartlett in an attempt to develop an electrochemical sensor free of the requirement of an enzyme.

Furthermore, the combination of familiar elements is likely to be obvious when it does no more than yield predictable results. The simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395–97 (2007) (see MPEP 2143).

Consequently, it would have been obvious to one of ordinary skill in the art to substitute the electrode of Bartlett with the device used in the method of Marincic in an attempt to develop an electrochemical sensor free of the requirement of an enzyme.

Finally, Evans suggest the use of the mesoporous platinum electrode in other electrochemical systems where surface processes were known to be rate limiting. See Evans page 1326. It was known in the art that the amperometric measurement of the direct oxidation of glucose suffered from sensitivity problems. See Marincic page 49. One of reasonable skill in the art would have considered surface processes to have an effect on the oxidation rate of glucose at platinum electrodes.

Additionally, Elliott teaches the improved characteristics of the microporous platinum electrode for the amperometric detection of organic species that "presently exhibit poor electrode kinetics." See Elliott page 7415.

Consequently, it would have been obvious taking the teachings of Evans and Elliott to use the mesoporous platinum electrode of Bartlett with the method of Marincic.

Regarding claims 11 and 12, Marincic teaches the use of platinum, a noble metal, as the material for the electrode. See page 44. Furthermore, Bartlett teaches the use of gold, a noble metal, and carbon as a suitable substrate or electrode. See col. 5 lines 14–16.

Regarding claim 13, Bartlett teaches the pore size of the platinum layer being between 2–50 nm. See col. 6 lines 25–30.

Regarding claim 14, Bartlett teaches the mesoporous platinum layer having a thickness anywhere between 1 to 200,000 nm, but preferably between 10 to 20,000 nm. See col. 5 lines 33–37.

Regarding claims 15 and 16, Marincic teaches the use of the method for detecting a biochemical substrate where the substrate is glucose. See page 43.

Moreover, Bartlett also teaches the use of the mesoporous platinum layer in the detection of glucose. See col. 9 line 27. Furthermore, although Marincic teaches specifically the detection of glucose in a simulated physiological solution, Marincic discloses that the ultimate use of the method would be for an implantable glucose that would detect glucose concentration in interstitial fluid. See page 43.

Regarding claim 17, Marincic teaches the amperometric measurement of the current. See page 45.

Regarding claim 18, Marincic teaches the use of voltages within the range of -0.1 and 0.5 V vs. a reference electrode for the specified conditions. See page 44.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marincic and Bartlett as applied to claims 10–18 above, and further in view of "Chemical Sensors and Biosensors" by Brian R. Eggins (hereinafter referred to as "Eggins").

Regarding claim 19, Marincic teaches the use of a saturated calomel electrode ("SCE") as the reference electrode instead of a Ag/AgCl reference electrode. See page 43. However, it is well known in the art that the SCE electrode and the Ag/AgCl reference electrode are analogous aqueous reference electrodes either of which would work in the present method. See Eggins pages 16–18. Furthermore, the Supreme Court has found it to be obvious to one of ordinary skill in the art to substitute a known element for another that yields predictable results. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395–97 (2007) (See MPEP 2143).

Consequently, it would have been obvious to one of ordinary skill in the art to have made the substitution of a Ag/AgCl reference electrode for the SCE electrode.

Regarding claim 20, Marincic teaches the method for the detection of a biochemical substrate, specifically glucose, with a concentration of glucose ranging from 0 to 20 mM, where the current generated is proportional to the concentration of glucose. See page 44–46.

Please note that in interpreting this claim the examiner is interpreting the term “proportional” to include direct proportionality, inverse proportionality, exponential proportionality and logarithmic proportionality.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. These references include:

1. Attard et al., (U.S. Patent No. 6,203,925) teaches a mesoporous platinum layer on an electrode and its potential uses as an electrode material in a biosensor for the measurement of glucose.
2. Schick et al., (U.S. Patent No. 4,127,448) teaches the amperometric non-enzymatic method of detecting glucose using a platinum electrode electrodeposited with lead-oxide and nickel-oxide.
3. Marincic et al., “Electrochemical Glucose Oxidation on a Platinized Electrode in Krebs-Ringer Solution" J. Electrochem. Soc.: Electrochemical Science and Technology 126 (10), 1687–1692 (1979) teaches that increasing the surface roughness of the platinum electrode, at higher glucose concentrations, increases the electrodes sensitivity.

4. Brabec V., "Electrochemical Oxidation of Nucleic Acids and Proteins at Graphite Electrode: Qualitative Aspects" J. of Electroanal. Chem. 116, 69–82 (1980) teaches the use of a graphite electrode for the direct oxidation of various proteins and amino acids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN D. RIPA whose telephone number is 571- 270-7875. The examiner can normally be reached on Monday to Friday, 9:00 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Sines can be reached on 571-272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. D. R./

Examiner, Art Unit 4111

/Brian J. Sines/
Supervisory Patent Examiner, Art Unit 4111